FEB 1 4 2003

elan K023407

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Summary of 510(k) Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC PAK Creatinine Reagent Kit is intended for the quantitative determination of creatinine in serum, plasma and urine. Creatinine results are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis and as a calculation basis for measuring other urine analytes. The ATAC PAK Creatinine Reagent determines creatinine through the reaction of creatinine with alkaline picrate. The initial rate of absorbance increase at 510 nm is proportional to the creatinine concentration of the sample. The ATAC PAK Creatinine Reagent Kit is substantially equivalent to the Beckman Synchron CX Creatinine Reagent, product no. 443340, which is currently marketed by Beckman Coulter, Inc. of Brea California.

The effectiveness of ATAC PAK Creatinine Reagent Kit on the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of creatinine using the ATAC PAK Creatinine Reagent is linear from 0.2 to 25 mg/dL, as shown by the recovery of linearity standards that span the usable range. Regression statistics, which are forced through the origin, compare standard recoveries to standard values. These statistics are shown below.

(ATAC Recoveries) = 0.997 x (Standard Value), $r = 0.9998$, $s_{y.x} = 0.19$ mg/dL, $n = 27$

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the methods described in NCCLS Guideline EP3-T, are shown below.

Precision of Creatinine Recoveries in mg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	120	0.7	0.05	6.9%	0.05	7.4%
Serum 2	120	4.1	0.06	1.6%	0.10	2.5%
Serum 3	120	7.2	0.18	2.5%	0.24	3.3%
Urine 1	120	3.6	0.10	2.8%	0.12	3.3%
Urine 2	120	14.8	0.42	2.9%	0.60	4.0%

Mixed serum, plasma and diluted urine specimens, collected from adult patients, were assayed for creatinine using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares linear regression and the following statistics were obtained.

Serum/Plasma Comparison
ATAC 8000 = 0.07 mg/dL + 0.956 x Competitive Reagent
$r = 0.998$ $n = 200$ range = 0.4 - 8.7 mg/dL

Urine Comparison
ATAC 8000 = 0.02 mg/dL + 0.960 x Competitive Reagent
$r = 0.998$ $n = 96$ range = 0.6 - 24.7 mg/dL

A specimen containing 1 mg/dL creatinine will produce an absorbance change of approximately 0.017 A on the ATAC 8000 Random Access Chemistry System.

The 24 hour calibration stability claim and the 7 day and 14 day on board reagent stability claims are documented through the assay of serum controls and urine pools over the claimed periods. In all cases, the total imprecision of creatinine recoveries over the test periods are less than 0.2 mg/dL or 5%.

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics
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Re: k023407
Trade/Device Name: ATAC PAK Creatinine Reagent
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: CGX; JIS
Dated: January 21, 2003
Received: January 21, 2003

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023407

Device Name: ATAC PAK Creatinine Reagent

Indications for Use:

The ATAC Creatinine Reagent Kit, the ATAC Calibrator and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of creatinine in serum, plasma and urine. Creatinine results are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis and as a calculation basis for measuring other urine analytes.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023407

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)